K093089

NOV 18 2009

8. 510(k) Summary

Sponsor:	Robert Reid Inc. 4-22-2, Koishikawa, Bunkyo-ku Tokyo 112-0002 Japan Phone +81-3-3830-7375 Fax +81-3-3830-7376
Contact Person:	Teiji Nakamura, Marketing Director
Proposed Trade Name:	Magnum Nail
Device Classification	Class II
Classification Name:	Rod, fixation, intramedullary and accessories
Regulation:	888.3020
Device Product Code:	HSB
Device Description:	The Magnum Nail consists of nails, distal bone screws, cannulated lag screws, cannulated blades and set screws in a variety of sizes to accommodate differing anatomic requirements.
Intended Use:	The Magnum Nail is intended for use in fixation of stable and unstable fractures of the proximal femur. The types of proximal femoral fractures include pertrochanteric, intertrochanteric, basal neck fractures, high subtrochanteric fractures and combinations of these fractures. The Magnum Nail is also indicated for use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures and revision procedures.
Materials:	The Magnum Nail components are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.
Substantial Equivalence:	Documentation was provided which demonstrated the Magnum Nail to be substantially equivalent to previously cleared devices (Fixion™ Interlocking Proximal Femoral Nailing System, K010988 and Trochanteric Fixation Nail System, K011857). The substantial equivalence is based upon equivalence in basic design, intended use, indications, anatomic sites and mechanical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 13 2009

Robert Reid Inc.
% Karen E. Warden, Ph. D.
Consultant
8202 Sherman Road
Chesterland, Ohio 44026-2141

Re: K093089
Trade/Device Name: Magnum Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 28, 2009
Received: October 1, 2009

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. Indications for Use Statement

510(k) Number: K093089

Device Name: **Magnum Nail**

Indications for Use:

The Magnum Nail is intended for use in fixation of stable and unstable fractures of the proximal femur. The types of proximal femoral fractures include pertrochanteric, intertrochanteric, basal neck fractures, high subtrochanteric fractures and combinations of these fractures. The Magnum Nail is also indicated for use in osteotomy, nonunions and malunions, bone reconstruction following tumor resection, grafting and pathological fractures and revision procedures.

Prescription Use __X__ AND/OR Over-the-Counter Use_____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093089